America's Blood Centers

OUR MEMBERS SERVE 47 MILLION TIMES NATIONWIDE

725 15th Street, NW ♦ Suite 700 ♦ Washington, DC 20005 ♦ 202-393-5725 ♦ 1-888-USBLOOD ♦ FAX 202-393-1282
Web Site: http://www.americasblood.org ♦ e-mail: abc@americasblood.org

March 9, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 99D-4959: Guidance for Industry on the Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000

To Whom It May Concern:

America's Blood Centers (ABC) appreciates the opportunity to submit written comments on the Food and Drug Administration's (FDA) proposed Guidance for Industry on the Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings. ABC is the national network of nonprofit, independent community blood centers that represent 48 percent of the nation's blood supply. ABC members collect, test, process and provide local hospitals with volunteer blood from their communities. ABC members also provide a major share of the nation's tissue, marrow donor, stem cell, transfusion and blood-related diagnostic and therapeutic services.

Although the proposed Guidance referenced above applies to open advisory committee meetings convened by the Center for Drug Evaluation and Research (CDER), and ABC is primarily concerned with the regulation of biologics, we believe this is an important topic and one on which CDER and the Center for Biologics Evaluation and Research (CBER) should maintain consistent policies.

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General Comments

America's Blood Centers, under the Coalition for Blood Safety (formerly known as the Coalition for Regulatory Reform) has made recommendations to FDA in the past about decision-making, particularly through the Blood Products Advisory Committee (BPAC). At one time, CBER had used its BPAC for recommendations on controversial issues. However, the committee structure and time allotted to an issue rarely allow the development of consensus on controversial issues. We believe the decision to restructure the committee to remove "industry bias" has exacerbated this problem.

As we have stated in the past, ABC recommends:

- That FDA consult the Policy and Guidance Handbook for FDA Advisory Committees, addressing the issue of committee balance, and consider recommendations of the Institute of Medicine's Committee to Study HIV Transmission Through Blood and Blood Products, which supported "a proper balance between members who are connected with the blood and blood products industry and members who are independent of industry."

- That FDA utilize expertise available in the blood banking and plasma community to review subjects and prepare background documents for the committee. This would allow more thorough review of the subjects, including analysis of the operational impact of proposed regulations prior to presentation to BPAC.

- That FDA allow time for input of committee members and outside organizations on the agenda.

- That FDA make its position known to the public before the meeting to allow interested organizations to participate more effectively. Also, FDA should make supporting documents not prohibited from disclosure available to the public in advance of the meeting. This would include published agendas with a synopsis of issues to be considered and an idea of what questions will be asked so that industry may develop relevant and useful public comments.

- That FDA promote more interaction between BPAC and FDA so the committee better understands its role and the goals of the agency. This would include discussing the format of questions to the committee in advance and accepting input from the committee.

- That FDA translate recommendations of the committee into regulation (or lack of regulation) in a more timely manner.

- That FDA identify, in advance, major controversial issues that may require the placement of some consensus development process prior to a presentation of the issue before BPAC. One model already used by FDA is the NIH Consensus Development Conference.

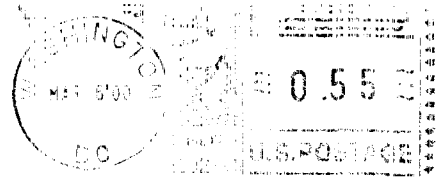
In testimony before the U.S. House of Representatives Commerce Committee's hearing on the safety and availability of the nation's blood supply on October 19, 1999, blood industry representatives reiterated the need for proper representation of the blood service community on bodies that advise FDA. In his testimony, America's Blood Centers President Celso Bianco, M.D., cited the 1996 Institute of Medicine study, which recommended that FDA strike a proper balance in committee membership and noted the lack of blood community representatives on FDA's most important Blood Products Advisory Committee (BPAC). We believe that a "proper balance" would mean representation from each of the major sectors of the blood community: independent blood centers, the American Red Cross, hospital blood banks, and the plasma industry. ABC considers correction of the current imbalance to be a very high priority.

Once again, ABC appreciates the opportunity to comment on FDA's proposed Guidance for Industry on the Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings. Should you have any questions concerning our comments, please feel free to contact Kristen Smith (202-393-5725, x19) or by e-mail, krsmith@americasblood.org.

Sincerely,

Celso Bianco, M.D.
President

America's Blood Centers
OUR MEMBERS SERVE COMMUNITIES NATIONWIDE
725 15th Street, NW • Suite 700
Washington, DC 20005



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